

PTO/SB/21 (07-06)

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## TRANSMITTAL FORM

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		Application Number	10/525,292-Conf. #6073
		Filing Date	October 27, 2005
		First Named Inventor	Hans-Juergen KRAUSE
		Art Unit	1700
		Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission		Attorney Docket Number	BBI-185US

### ENCLOSURES (Check all that apply)

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### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

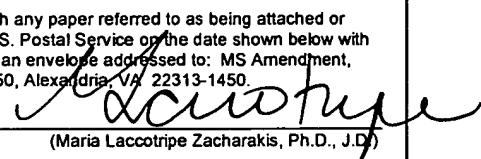
Firm Name	LAHIVE & COCKFIELD LLP		
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Printed name	Maria Laccotripe Zacharakis, Ph.D., J.D.		
Date	October 30, 2006	Reg. No.	56,266

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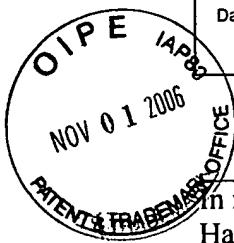
Dated: October 30, 2006

Signature: (Maria Laccotripe Zacharakis, Ph.D., J.D.)

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Dated: October 30, 2006      Signature:   
(Maria Laccotripe Zacharakis, Ph.D., J.D.)

Docket No.: BBI-185US  
(PATENT)



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Hans-Juergen Krause *et al.*

Application No.: 10/525,292

Confirmation No.: 6073

Filed: October 27, 2005

Art Unit: 1700

For: FORMULATION OF HUMAN ANTIBODIES  
FOR TREATING TNF-ALPHA  
ASSOCIATED DISORDERS

Examiner: Not Yet Assigned

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

### INFORMATION DISCLOSURE STATEMENT (IDS)

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

In accordance with 37 CFR 1.98(a)(2)(ii), Applicants have not submitted copies of U.S. patents. Applicants submit herewith copies of foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information

as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 12-0080, under Order No. BBI-185US.

Dated: October 30, 2006

MLZ/JAM/mch

Respectfully submitted,

By

  
Maria Laccotripe Zacharakis, Ph.D., J.D.  
Registration No.: 56,266  
LAHIVE & COCKFIELD, LLP  
One Post Office Square  
Boston, Massachusetts 02109-2127  
(617) 227-7400  
(617) 742-4214 (Fax)  
Attorney/Agent For Applicant



PTO/SB/08a/b (07-06)

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

				<b>Complete if Known</b>	
Application Number		10/525,292-Conf. #6073			
Filing Date		October 27, 2005			
First Named Inventor		Hans-Juergen KRAUSE			
Art Unit		1700			
Examiner Name		Not Yet Assigned			
Sheet	1	of	1	Attorney Docket Number	BBI-185US

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
A1*	US-5,945,098	08-31-1999	Sarno et al.		
A2*	US-6,024,938	02-15-2000	Corbo et al.		
A3*	US-6,090,382	07-18-2000	Salfeld et al.		
A4*	US-6,171,586	01-09-2001	Lam et al.		

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
B1	EP-0486526-B1		05-27-1992	Peptide Technology Ltd.		
B2	WO-97/04801-A1		02-13-1997	Genentech Inc.		
B3	WO-98/22136-A2		05-28-1998	Boehringer Mannheim GmbH		
B4	WO-98/56418-A1		12-17-1998	Genentech, Inc.		
B5	WO-01/47554-A1		07-05-2001	Chugai Pharmaceutical Co. Ltd. et al.		Abstr.
B6	EP-1174148-A1		01-23-2002	Yamanouchi Pharmaceutical Co. Ltd.		
B7	WO-02/12502-A2		02-14-2002	Centocor, Inc.		
B8	EP-1254666-A1		11-06-2002	Chugai Seiyaku Kabushiki Kaisha		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
C1	Cleland, Jeffrey L. et al, "A Specific Molar Ratio of Stabilizer to Protein is Required for Storage Stability of a Lyophilized Monoclonal Antibody," <i>Journal of Pharmaceutical Sciences</i> , Vol. 90(3):310-321 (2001)		
C2	Hillgren, Anna et al, "Protection mechanism of Tween 80 during freeze-thawing of a model protein, LDH," <i>International Journal of Pharmaceutics</i> , Vol. 237:57-69 (2002)		
C3	Holt, Lucy J. et al, "Domain antibodies: proteins for therapy," <i>Trends in Biotechnology</i> , Vol. 21(11):484-490 (2003)		
C4	International Search Report for Application No. PCT/IB03/04502, dated May 26, 2004		
C5	International Preliminary Examination Report for Application No. PCT/IB03/04502, dated February 14, 2005		

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<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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Application No. (if known): 10/525,292

Attorney Docket No.: BBI-185US

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